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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)											
		S63.2-11032-US01											
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		Application Number	Filed										
		10/749821	12/31/2003										
		First Named Inventor											
		Burgmeier et al.											
		Art Unit	Examiner										
		1791	Monica Anne Huson										
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table border="0"><tr><td><input type="checkbox"/> applicant/inventor.</td><td>/Walter J. Steinkraus/</td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td>Signature Walter J. Steinkraus</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number 29592</td><td>Typed or printed name 952-563-3000</td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td>Telephone number 4/10/2009</td></tr><tr><td></td><td>Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>				<input type="checkbox"/> applicant/inventor.	/Walter J. Steinkraus/	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Signature Walter J. Steinkraus	<input checked="" type="checkbox"/> attorney or agent of record. Registration number 29592	Typed or printed name 952-563-3000	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	Telephone number 4/10/2009		Date
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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Burgmeier, et al  
Application No.: 10/749821  
Filed: December 31, 2003  
For: MEDICAL DEVICE WITH VARYING PHYSICAL PROPERTIES AND  
METHOD FOR FORMING SAME  
Examiner: Monica Anne Huson  
Group Art Unit: 1791

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Docket No.: S63.2B-11032-US01**

**REASONS FOR PREAPPEAL CONFERENCE**

Independent claim 20 is directed to an method of forming a polymeric part for a medical device that involves emission of mass of material such that it has at least two regions located within in a single layer of the emitted mass along the length thereof with differing amounts of crystallization modifier in the two regions of the single layer. The method allows one to vary physical properties within the layer. This provides a method of varying the physical properties along the length of a device such as a catheter or balloon. Particular embodiments, to which some of the dependent claims are directed relate to the use in making tubes for making balloons, and in making balloons produced therewith, including location of the modifiers at particular balloon sites along the length that provide specific disclosed benefits.

**Claim Rejections 35 USC §103**

Claims 20-25, 29-30, 6-7, 9-11, and 13-14 have been rejected as obvious from Wang, et al, US 6,465,067 ("Wang") in view of Forte et al US 2003/005161 ("Forte").

When determining obviousness using a combination of references, the prior art must be considered as a whole, without the benefit of the impermissible hindsight vision afforded by the claimed invention. The prior art must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the applicant's invention. Taking into account the evidence of common knowledge and the common sense of the skilled person, there must be some evidence of a suggestion, teaching or motivation that would have led

the skilled person to produce the invention as claimed. *In re Translogic Technology Inc.*, 84 USPQ2D 1929, 1937 (Fed. Cir. 2007); *Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2D 1196, 1201-1202 (Fed. Cir. 2008). It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. MPEP 2142, explicitly requires that the examiner step backward in time to determine whether the invention as a whole would have been obvious to a skilled person without knowledge of the invention. Similarly *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (US Sup. Ct. 2007) states: "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

The rejection clearly fails to establish *prima facie* obviousness of the invention of independent claim 20. At least for this reason the rejection fails as to all of the rejected claims.

Wang shows variation of composition between different layers of an tubing extrusion for a medical balloon, it does not show or suggest variation between two regions of a single layer of material. The location of the differences are in a direction radially through the thickness of the tubing, not along the length. The Office Action does not explain why a skilled person would have sought to modify a balloon or balloon tubing of Wang to have variation of crystallization modifier along the length of a single layer, rather than between different layers.

The Office Action contends that Forte "shows that it is known to carry out a method of making ***an extruded polymeric article*** wherein the crystallization modifier can be present ***in any desired distribution or fashion***, depending on the desired article" (emphasis added). This assertion is clearly wrong. The assertion attributes to Forte teachings that are not found or suggested anywhere in the document.

Firstly, as to "an extruded polymeric article," Forte pertains to packaging film that tears easily. It relates neither to extruded polymer articles generally nor to medical devices particularly. The Office Action fails to articulate a reason why one would combine the Wang et al and Forte documents in fashioning a medical device part.

In particular why would one look to techniques for preparing tearable packaging

film when forming medical balloons of the type described by Wang? The Final Office Action completely ignores this question that was posed in the 11/26/2008 response. Generally one wants medical balloons to have high tear strengths. Forte's tearable film compositions would not be of interest to a person making tubing for a Wang balloon.

Secondly, Final Action, contends that it has articulated a reason for modification in stating that Forte shows a method of "making extruded polymeric article wherein the crystallization modifier can be present in any desired distribution or fashion, depending on the desired article." This statement is false, but even if we treated it as true for the purposes of argument, it is not a reason for modification of Wang et al to vary composition along the length of a single layer. This is exactly the "mere conclusory statement" that the *KSR* decision ***explicitly prohibits***. Wang teaches to vary properties between layers, not within layers. Forte doesn't provide a reason to vary the properties within any of Wang's layers. The Examiner is merely assuming that the skilled person wants to make the claimed variation. Nothing in either Wang or Forte justifies this assumption. The Final Action simply ignores the requirement that the prior art must make obvious the subject matter as claimed, not merely some generic process broader than the claims at issue.

Thirdly, to support the "any desired distribution or fashion" assertion, the Final Office Action cites paragraphs 0013, 0014, 0036, 0040, 0041. Those paragraphs are reproduced below in their entirety with emphasis added:

[0013] The film may be a single layer film or a multilayer film. In multilayer embodiment, skin layers with standard homopolymer polypropylene and no hcPP may encapsulate a core layer that includes hcPP and standard homopolymer polypropylene resins. Because the more crystalline core layer is positioned between two less crystalline layers, the film is more easily processed and has increased durability. Another multilayer embodiment has a core layer and two skin layer, each of the three layers containing hcPP resin.

[0014] The amount of hcPP resin contained within each layer may vary according to the properties desired in the film. ***For example, all layers may contain the same amount of hcPP resin.*** As a result, the layers have similar or the same viscosities and may be simultaneously co-extruded on standard co-extrusion equipment without the addition of processing acids.

[0036] The inventive film may be a single layer film or multilayer film, extruded by conventional extrusion or coextrusion processes well known in the art. ***The polymer resins for each layer are melted and mixed with any additives in an extruder.*** The resins

are then extruded (or coextruded in the case of multilayer films) through a slot die.

[0040] In multilayer embodiments ***the core layer preferably contains greater amounts of hcPP than the skin layers***. In some embodiments, one or both of the skin layers may include no highly crystalline polypropylene. An embodiment ***with at least one hcPP-free skin layer*** will make the film more durable because it protects the crystalline, easy to tear core layer. Similarly, ***skin layers with less hcPP than the core*** provide some protection and added durability.

[0041] ***Alternatively, the skin layers and core layer may have identical amounts of hcPP***. As discussed above, coextrusion of layers with similar or the same viscosities may be simultaneously coextruded on standard coextrusion equipment without the addition of processing agents to increase or decrease viscosity of the resins. Therefore, embodiments with similar or identical amounts of hcPP may have good processing efficiency.

Nothing in these paragraphs says anything about a crystallization modifier being present "in any desired distribution or fashion." Note specifically that the Final Action has improperly taken the first sentence from paragraph 40:

The amount of hcPP resin contained within each layer may vary according to the properties desired in the film

out of the context provided by the very next sentence:

***For example, all layers*** may contain the same amount of hcPP resin.

which exemplifies compositions of ***different layers***, not of the same layer. The Final Office Action clearly does not step backward in time to read this art in the context it would have been given by a skilled person without knowledge of the invention, as required MPEP 2142. Nothing in the first quoted sentence above or anywhere else indicates that a person would desire to vary film properties of the tearable film along its length. The ***only*** variations discussed anywhere in the cited paragraphs are of variations between layers.

Review of Forte in its entirety reveals that when compositional variation is described it is either 1) a choice of a particular composition from a range of available compositions, or 2) compositional variation between layers. This is not "any desired distribution or fashion." No reasonable reading of Forte et al as a whole in the context it would have been given by a skilled person before the present invention would lead a skilled person to conclude that the document teaches or suggests use of any crystallization modifier in ***every*** possible distribution or fashion for ***any*** extruded article. The Final Action makes a fictionalized generalization that is

not justified by an objective prospective reading of Forte, and does so retrospectively - with reference to the applicant's disclosure. ***This is impermissible hindsight by definition.***

The rejection fails to articulate a reasonable basis for combining the Wang and Forte documents; fails to show any reason why one would be motivated to vary Wang's tubing composition in a single layer along the length of the extrusion as claimed; and is founded on an impermissible fictional reconstruction of the Forte teachings. At least for these reasons the claimed invention is not obvious from Wang in view of Forte. Withdrawal of the outstanding rejections is respectfully requested.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: April 10, 2009

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